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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,537	07/01/2004	Yasushi Fuchita	930011-2032	6430
7590 Frommer Lawrence & Haug 745 Fifth Avenue New York, NY 10151			EXAMINER VU, QUYNH-NHIU HOANG	
			ART UNIT 3763	PAPER NUMBER
			MAIL DATE 07/02/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/500,537

**Applicant(s)**

FUCHITA ET AL.

**Examiner**

QUYNH-NHU H. VU

**Art Unit**

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

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**DETAILED ACTION**

**DETAILED ACTION**

***Response to Amendment***

Amendment filed on 2/2/07 has been entered.

Claims 1-14 are present for examination.

Applicant's arguments filed on (date) have been fully considered but are not persuasive. Please see the rejection below .

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9-12, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Higo et al. (US 6,259,946).

Higo et al. discloses an iontophoresis device comprising a base film (3a), an electrode layer (3b), a gel (6), and a sheet member (2) having a property for allowing said gel to permeate therein (water retention, or no woven fabric, col. 3, lines 7-28). The sheet member has a ring like shape and a concave space to receive said gel. It is noted that the sheet member serves to hold the electrolyte/gel and made of material with excellent workability, flexibly and suitable shape retention (col. 3, lines 7-9). Therefore, the retention force resulting from the permeated portion of the gel is sufficient to retain the gel in the region to receive the gel.

Additionally, it is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e. "the retention force resulting from...receive the gel", a functional limitation, does not impose any structural limitation upon the claimed apparatus which

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differentiates it from a prior art reference disclosing the structural limitations of the claim, see *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974).

The electrode has a main body portion comprising said gel and a lead part extending from said main body portion. The electrode layer is disposed between said base film and said sheet member. (See Figures 1-4). The base film is composed of polyethylene terephthalate and conductive silver paste. (See Column 5 Lines 43-45).

It appears that Higo et al. reasonably discloses every element of claims 1-7 and 9-10.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Higo et al. in view of McAdams et al. (US 6,731,987).

Higo et al. discloses an iontophoresis device comprising a base film (3a), an electrode layer (3b), a gel (6), and a sheet member (2). The sheet member has a ring like shape and a concave space to receive said gel. The electrode has a main body portion comprising said gel and a lead part extending from said main body portion. The electrode layer is disposed between said base film and said sheet member. (See Figures 1-4) The base film is composed of polyethylene terephthalate and conductive silver paste. (See Column 5 Lines 43-45).

Higo et al. fails to disclose a support member; the sheet member covers completely the electrode layer in the region of the electrode layer to receive the gel.

McAdams et al. teaches a medical electrode comprising an electrode layer (5), the sheet member/intermediate layer (6) covers completely the electrode layer (4 or 5) in the region of the electrode

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layer to receive gel, an electrochemical layer (7), and support member (8). The support member is disposed at a peripheral edge of said electrochemical layer and provides insulation (See Figure 2).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Higo et al. with the teachings of McAdams et al. to provide an iontophoresis device comprising a support member and have enough retention force to retain the gel.

### ***Response to Arguments***

Applicant's arguments filed 2/2/07 have been fully considered but they are not persuasive.

Applicant argues that Higo does not disclose a sheet member "having a property for allowing said gel to permeate therein...wherein, when said gel is disposed on the sheet member in the region to receive the gel, the retention force resulting from the permeated portion of the gel is sufficient to retain the gel in the region to receive the gel".

In response, Please see rejection above for more explanation. Furthermore, this limitation above is not novelty in the art. Applicant Admitted Prior Art as discussed on pages 1-2 and 4 of Specification.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu  
Examiner  
Art Unit 3763